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510(k) Summary
AMS Perigee™ System

510(k) Number K040623

Date of Summary Preparation:
March 8, 2004

Submitter/Contact Person:
Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343

Phone: (952) 930-6000
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Device Name and Classification:
Trade Name: AMS Perigee™ System
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Mesh, polymeric
Product Code: FTL
Classification: Class II

Manufacturing Location:
American Medical Systems, Inc.
10700 Bren Rd. West
Minnetonka, MN 55343

Predicate Devices:
AMS Sparc Sling System – K011251
AMS Monarc Sling System – K023516
AMS BioArc – K030123
AMS Large Pore Polypropylene Mesh – K033636, K040521

Indications for Use:
The Perigee™ System is intended for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior vaginal wall prolapse.

Device Description:
The Perigee™ System consists of needles and connectors used to pass a polypropylene mesh for support of the anterior vaginal wall.

Summary of Testing
The mesh used in the Perigee™ System has been tested in accordance with FDA's Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh and has been shown to be equivalent to the listed predicate devices. In

addition, the other components have demonstrated substantial equivalence to the predicate devices in terms of mechanical performance and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Ms. Elsa A. Linke
Regulatory Affairs Specialist
American Medical Systems
10700 Bren Road W.
Minnetonka, Minnesota 55343

Re: K040623
Trade/Device Name: AMS Perigee™ System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: II
Product Code: FTL
Dated: March 8, 2004
Received: March 9, 2004

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K040623

Device Name: AMS Perigee™ System

Indications for Use: The Perigee™ System is intended for the placement of graft material in the anterior vaginal wall via the obturator foramen for the treatment of anterior vaginal wall prolapse.

Prescription Use___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K040623